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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/543,022	09/14/2006	Niva Shapira	32467	4059

67801 7590 11/16/2010

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EXAMINER	
BUCKLEY, AUDREA	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
11/16/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/543,022	SHAPIRA ET AL.	
	Examiner	Art Unit	
	AUDREA J. BUCKLEY	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,63-66,68-70,74,75 and 77-87* is/are pending in the application.

4a) Of the above claim(s) *69,70 and 82-87* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,63-66,68,74,75 and 77-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/10/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Acknowledgement is made of Applicant's claim amendments and remarks/arguments filed 8/12/2010.

Claims 1, 63-66, 68, 74, 75, and 77-81 are pending and under consideration herein.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 5/10/2010 is in compliance with the provisions of 37 CFR 1.97 and has been considered.

Withdrawn Claim Rejections

The rejection of claims 1, 67, and 75-78 under 35 U.S.C. 112, second paragraph is withdrawn in light of Applicant's amendments to the claims filed 8/12/2010.

The rejection of claims 1, 66, 68, 74, 76, and 79-81 under 35 U.S.C. 102(b) as being unpatentable over Lambert et al. as evidenced by Handelman et al. is withdrawn in light of Applicants' amendments to the claims filed 8/12/2010.

The rejection of claims 1, 63, 64, 66-68, 74, 76, and 79-81 under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. as evidenced by Handelman et al. is withdrawn in light of Applicants' amendments to the claims filed 8/12/2010.

The rejection of claim 67 under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. as evidenced by Handelman et al. and further in view of Grimberg is withdrawn in light of Applicants' amendments to the claims filed 8/12/2010.

The rejection of claim 67 under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. as evidenced by Handelman et al. and further in view of Howard et al. is withdrawn in light of Applicants' amendments to the claims filed 8/12/2010.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 63-66, 68, 74, 75, and 77-81 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the antioxidant" in lines 5 and 6. It is unclear what is the relationship between "the antioxidant" and "the antioxidant component". Is the antioxidant component a component that has antioxidant activity, is it simply a portion of an antioxidant (a component part of an antioxidant), or is it a composition comprising a variety of molecules, one of which is an antioxidant molecule? Moreover, if there is "at least one antioxidant component", then there may be more than one antioxidant, and it is unclear to which antioxidant "the antioxidant" refers. For the purpose of search and examination, the "at least one antioxidant component" has been interpreted as the antecedent to "the antioxidant".

New Grounds of Rejection as Necessitated by Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 63-66, 68, 74, 77-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. (US 6,284,265 B1, patented Sep.

2001) as evidenced by Handelman et al. ("Antioxidant Capacity of Oat Extracts", J. Agric. Food Chem., 1999, 47, 4888-4893) and further in view of Grimberg (US 5,667,802, patented Sep. 1997).

Regarding claims 1, 66, 68, and 81, Lambert et al. teach an antacid formulation comprising an antacid or mixture of antacids, oil, an antioxidant, and a carrier (see abstract, in particular). In a particular formulation, the embodiment comprises 10.0% dihydroxy-aluminum-sodium-carbonate, 10% aluminum phosphate, 2.75% dicalcium phosphate, and 0.7% calcium carbonate, all antacid components totaling 23.45% by mass of the total formulation further comprising 70.45% by mass of a carrier, 6.0% soybean oil (a lubricant), and 0.1% of the antioxidant ethoxyquin (see column 3, lines 32-40). In terms of the carrier, Lambert et al. teach that the 70.45% carrier is broken down into 30.45% ground wheat, 20.0% spray dried whey, and 20% steam rolled oats, which inherently comprise plant-derived antioxidants and phenol derivatives as evidenced by Handelman et al. As to claim 65, it is noted that ethoxyquin and oat compounds serve as two distinct antioxidants. Regarding claim 74, Handelman et al. teach the antioxidant capacity of oat extracts wherein several classes of compounds with antioxidant activity, including vitamin E tocols, flavonoids, and non-flavonoid phenolic acids, have been identified in oat (see page 4888, Introduction, paragraph 1). Since rolled oats comprise 14.1% (20% of 70.45%) of the total antacid formulation, this embodiment of Lambert et al. reads on instant claims 1 and 77 since the antioxidant components comprise 14.2% by weight of the total formulation and the antacid comprises 23.5% by weight of the total formulation;

that is, the relative amount of the antioxidant components is 37.8% by weight of the total antacid and antioxidant component weight.

As to claim 78, it is noted that the 37.8% quantity of antioxidant components is 40% when expressed to one significant figure as in pending claim 78. MPEP 2144.05 states that "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Similarly, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). Therefore, it is the Examiner's position that this quantity would have rendered obvious the value of 40% by weight as in pending claim 78.

As to claims 63 and 64, it is the examiner's position that the capability of decreasing free radical and peroxide generation as in claim 63 and the ability to decrease at least two fold concentration of free radicals and peroxides as in claim 64 are result effective variables because changing them clearly will affect the type of product obtained. See MPEP 2144.05(b). Case law holds that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." See In re Boesch, 617 F.2d 272, 205

USPQ 215 (CCPA 1980). In view of this, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize appropriate quantities of the antioxidant and antacid components in order to control the potency and efficacy of the antacid formulation, including those quantities within the scope of the present claims, so as to produce desired end results.

As to claims 79 and 80, Lambert et al. teach that the antacid formulation can be pelletized for oral administration (see column 3, lines 45).

As to claim 1, Lambert et al. do not quantify the reduction of pH as a result of antacid administration.

However, Grimberg teaches an antacid composition employing a variety of antacids such as magnesium oxide. Grimberg studies the change in pH as a function of time upon administration of the antacid formulation. For example, Figure 7 illustrates the pH changes with magnesium hydroxide, and it is noted that the pH unit is increased by at least one pH unit as required by the instant claim.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to quantify the pH increase as a measure of efficacy of the antacid formulation and to formulate an antacid composition having the pH change deemed effective as taught by Grimberg. One of ordinary skill in the art at the time the invention was made would have been motivated to do so in order to more fully characterize the antacid properties and efficacy in the formulations of Lambert et al. as taught by Grimberg.

Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. (US 6,284,265 B1, patented Sep. 2001) as evidenced by Handelman et al. ("Antioxidant Capacity of Oat Extracts", J. Agric. Food Chem., 1999, 47, 4888-4893) and in view of Grimberg (US 5,667,802, patented Sep. 1997) as applied to claims 63-66, 68, 74, 77-81 above and further in view of Howard et al. (US 6,099,854, patented Aug. 2000).

The teachings of Lambert et al., Handelman et al., and Grimberg are delineated above. These references do not teach a polyphenol antioxidant as in pending claim 75.

Regarding claim 75, Howard et al. teach a flavonol-containing composition wherein at least 25% of the composition includes polyphenols and at least 1.0% is flavonol (see abstract, in particular), both of which are plant-derived (see column 6, lines 1-3; see also, column 25, lines 46-50). Howard et al. more preferably teaches that the plant derived material comprises at least 35% polyphenols or more preferably at least 45% polyphenols (see column 5, lines 65-67).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to include the polyphenol and flavonol plant-derived antioxidants as disclosed in the teaching of Howard et al. in the formulation of Lambert et al., which also teaches the benefits of the antioxidant component. All these formulations are to be taken orally as a health benefit; Lambert et al. teaches that an antioxidant benefits the antacid formulation since the antioxidant functions to prevent oxidation and breakdown of certain

components of the composition prior to consumption (see column 3, lines 9-12). Lambert et al. generally teaches the benefits of antioxidants but teaches only one example; as such, the skilled artisan would have been motivated to look to the teaching of Howard et al. which discloses consumable antioxidants and further teaches the added health benefits of these particular polyphenol antioxidants. Further, the skilled artisan would have been motivated to implement the polyphenol antioxidants for the reasons deemed desirable by Howard et al., including the convenience of obtaining the active agent (see column 7, lines 14-16), the known health benefits of polyphenols (i.e., desirable antioxidant activity in LDL) (see column 13, lines 4-7).

Response to Arguments

Applicant's arguments presented 8/12/2010 have been fully considered but are moot in light of amendment. As noted above, all rejections previously presented and not re-iterated herein are withdrawn. Because the new grounds of rejection under 35 U.S.C. 112, second paragraph are issued herein, the instant Office action is non-final. Applicant's positions against cited references are summarized and responded to as follows.

Applicant argues that the Lambert reference does not teach the proportions of antacid and antioxidant as in amended claim 1. Applicant iterates that Lambert teaches the inclusion of the antioxidant for a purpose alternate to that of the instant application and concludes that Lambert does not provide motivation for including more than 1.0% antioxidant. In reply, the Examiner

disagrees for the reasons articulated in the rejection above. Essentially, the grounds of rejection are maintained, and Applicant's position is not persuasive since the antecedent of "the antioxidant" is the "at least one antioxidant component". As such, the rolled oats in the teaching of Lambert constitute the antioxidant component required in the instant claim. Particularly and as evidenced by Handelman, the formulations of Lambert et al. necessarily include a quantity of antioxidant components as in pending claim 1(b).

The Examiner notes that the claim language "for potentiating antioxidative activities" as in pending claim 1 recites an intended use which is not granted patentable weight as it imparts no structural limitations to the claimed composition. Additionally, MPEP 2144 states that the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. Otherwise, Applicant's arguments appear to be directed to a method of using an antacid composition rather than the composition itself which is the statutory class instantly claimed. Finally, Applicant takes the position that if one were to modify the antacid formulation of Lambert, one would not produce the instant invention. In reply, it is noted that the rejection relying on Lambert alone has been withdrawn; Applicant's arguments are moot in light of amendment.

Regarding the rejection of former claim 67 over Lambert in view of Grimberg under 35 U.S.C. 103(a), Applicant's argument has been considered but is moot in light of amendment and the relevance of the Grimberg reference is maintained.

Regarding the rejection of former claims 65, 75, 77, and 78 over Lambert in view of Howard, Applicant traverses. Applicant takes the position that the ranges taught by Howard do not overlap the ranges recited in the claims; this argument has been considered but is not persuasive for the reasons of record and as articulated above.

Applicant takes the position that the cited art fails to suggest using a proportion of antioxidant recited in the claims. This argument is not persuasive in view of the Lambert reference as evidenced by Handelman et al. for the reasons of record.

Applicant argues that there is no motivation to combine the teachings of Howard and Lambert. In reply, it is maintained that both Lambert and Howard teach orally administered antioxidants and that Lambert teaches the benefits of including antioxidants in an antacid formulation. Howard teaches the advantages of particular polyphenol antioxidants in orally administered formulations. Therefore, the relevance of these references is maintained.

Conclusion

No claims are found allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AUDREA J. BUCKLEY whose telephone number is (571)270-1336. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on (571) 272-3311.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AJB/

/Richard Schnizer/
Primary Examiner, Art Unit 1635